NOV 1 4 2003

K031646

510 (k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BAUSCH & LOMB® MULTI-PURPOSE SOLUTION NRC03

(TRADENAME TO BE DETERMINED)

1. **Submitter Information**

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14609

Contact Person: Paul G. Stapleton
Director, Regulatory Affairs

Telephone Number: 585-338-8172

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Care Solution

Proprietary Name: Bausch & Lomb Multi-Purpose Solution NRC03

3. **Predicate Devices**

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution, Alcon Opti-Free Express Multi-Purpose Disinfecting Solution and AMO Complete brand Multi-Purpose Solution have been selected as the predicate devices for Bausch & Lomb Multi-Purpose Solution NRC03.

4. **Description of the Device**

Bausch & Lomb Multi-Purpose Solution NRC03 is a sterile isotonic solution containing boric acid, sodium chloride, sodium phosphate, Hydranate® (hydroxyalkylphosphonate), poloxamer 407, polyquaternium-10, poloxamine 1107, purified water and preserved with polyaminopropyl biguanide (0.0001%). The product is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. The sterile solution is

contained in a plastic bottle with a tamper evident seal and is labeled with a lot number and expiration date.

5. Indications for Use

Bausch & Lomb Multi-Purpose Solution NRC03 is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) lenses as recommended by your eye care practitioner.

6. Description of Safety and Substantial Equivalence

A series of preclinical and clinical studies were completed on this product. The following studies have been completed:

Toxicology
A series of cytotoxicity and eye irritation studies of the Bausch & Lomb Multi-Purpose Solution NRC03 and lenses cycled in the solution were undertaken. In these studies, there was no evidence of toxicity.

Lens Compatibility
Lens compatibility studies were undertaken after cycling lenses in the solution. The results indicated that lenses were compatible with the solution.

Microbiology
Disinfection efficacy was evaluated according to the FDA Guidance document as well as modifications to established procedures. The results indicate satisfactory levels of disinfection efficacy.

Cleaning Efficacy
The cleaning efficacy of the solution has been evaluated through the determination of the Critical Micelle Concentration. The surfactant concentrations are well above the CMC for the individual surfactants.

The ability of the solution to prevent the deposition of protein has been established by the evaluation of protein present on the lens following solution usage in a no rub with a rinse regimen with a four (4) hour disinfection time. Protein deposition was significantly prevented as measured by Image Analysis.

The efficacy of the product to remove protein deposits measured by chemical analysis was evaluated with protein deposited lenses. The results indicated statistical equivalence between Test and Control.

Cleanliness Analysis of Clinical Lens Returns

The analysis of lens cleanliness from both Test and Control regimens indicates that these regimens are substantially equivalent when evaluated by Image Analysis.

Lens Wettability

Lens wettability over time has been assessed by measurement of contact angle and continued presence of wetting agents over time. The results indicated statistical significance for longer wetting ability over the controls.

Clinical Studies

A 3-month controlled, randomized study designed to evaluate the safety and efficacy of the Multi-Purpose Solution NRC03 was completed to demonstrate the safety and efficacy of the solution and substantial equivalence to the Control.

Substantial Equivalence

Bausch & Lomb Multi-Purpose Solution NRC03 is substantially equivalent to Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution, Opti-Free Express Multi-Purpose Disinfecting Solution and Complete brand Multi-Purpose Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Bausch & Lomb
C/O Paul G. Stapleton
Director, Global Regulatory Affairs
1400 N. Goodman St.
Rochester, NY 14609

Re: K031646
Trade/Device Name: Bausch & Lomb Multi-Purpose Solution NRC03
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: October 14, 2003
Received: October 15, 2003

Dear Mr. Stapleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14692-0450

Indications for Use Statement

510(k) Number (if known): K031646

Device Name: Bausch & Lomb Multi-Purpose Solution NRC03 (Tradename to be determined)

Indications for Use:

Bausch & Lomb Multi-Purpose Solution NRC03 is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care provider.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use X

Karen Warbington

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K031646